

App. No. 10/737,128

Filed December 15, 2003

Amendment dated January 4, 2006 in response to non-final Office Action of October 4, 2005

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### **REMARKS/ARGUMENTS**

Regarding the Applicant's Response to the non-final Office Action of 10/04/2005, Applicant respectfully requests that claims 1, 8, 17, 18, 23 be amended and claim 26 canceled as indicated above, and that the following remarks and arguments be considered.

Applicant asserts that the claims as amended comply with 37 C.F.R. §1.116 such that they are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

#### **I. Response to the Declaration**

The present Office Action initially addresses the Applicant's Declaration under 37 CFR 1.132 ("the Declaration"), submitted with the Applicant's previous Response of September 16, 2005. Specifically, the Examiner asserts that the Declaration is insufficient to overcome the rejection of claims 23 and 26 as set forth in the previous Office Action because "the specification and claims do not provide support for the facts set forth [in paragraph 10 of the Declaration,] nor are the limitations commensurate in scope of the claims." The Examiner also discusses the asserted insufficiency of paragraphs 13, 14, 16, 18 and 19 of the Declaration.

The Declaration was filed in order to traverse the Examiner's rejection of claims 23 and 26 in previous Office Actions. More specifically, the Declaration was filed in order to respond to the Examiner's contention that, in claims 23 and 26, "the ratio between the length of the distal section to the length of the intermediate section, and the ratio between the length of the proximal section to the length of the distal section, are a simple matter of design choice."

Applicant reiterates that the Examiner has never stated a statutory ground for the rejection of claims 23 and 26. Nevertheless, claim 26 has been canceled and claim 23 has been amended to exclude the ratio between the length of the distal section to the length of the intermediate section, and the ratio between the length of the proximal section to the length of the distal section. Applicant asserts that the Examiner's reproof of the Declaration, as it applies to the rejection of claims 23 and 26, is now moot in light of the current amendment of claim 23 and cancellation of claim 26.

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## **II. Drawings**

The drawings are objected to under 37 CFR 1.83(a) "because they are not scaled." Specifically, the Examiner asserts that, in the drawings, "... the ratio of the length of the distal section to the length of the intermediate section is not about 1.0 to about 2.0 and the ratio of the length of the proximal section to the length of the distal section is not about 2.0 to about 4.0", as claimed in claims 1, 17 and 23. Therefore, Examiner asserts that these ratios "must be shown [in the drawings] or the feature(s) canceled from the claims."

Claims 1, 17 and 23 have been amended to exclude the ratio between the length of the distal section to the length of the intermediate section, and the ratio between the length of the proximal section to the length of the distal section. Therefore, Applicant asserts that the drawings as filed are sufficient because they show every feature of the invention specified in the claims, as currently amended, and respectfully request that the objection to the drawings under 37 CFR 1.83(a) be withdrawn.

## **III. Specification**

The Specification is objected to under 35 USC 112, first paragraph because "it is replete with terms which are not clear, concise and exact." Specifically, the Examiner requires clarification because "it is unclear if the applicant intends to claim a tracheotomy or an endotracheal tube or if the applicant is calling a tracheotomy tube an endotracheal tube and using the term endotracheal tube to mean the same tube as tracheotomy tube or it may be the tubes are two separate tubes."

To clarify, the tube of the present invention is a "tracheotomy endotracheal tube," which is a specific type of endotracheal tube. The term "endotracheal tube" refers to any tube which is placed within the trachea of a patient, and a generic endotracheal tube can be inserted into the trachea via the mouth, the nose, or via a hole in the trachea. The term "tracheotomy endotracheal tube," as used in the present invention, thus refers to an endotracheal tube which is inserted specifically via a hole in the trachea.

The term "tracheotomy" is typically defined as a surgical procedure that creates a tracheostomy, and the term "tracheostomy" (also called a "tracheal stoma") is typically defined

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as an opening (or stoma) which is surgically created (via a tracheotomy procedure) in the windpipe (trachea) of an individual in order to bypass an obstruction of the upper airway, to allow air to get to the lungs, or to remove secretions within the airway. However, the terms "tracheostomy" and "tracheotomy" are typically used interchangeably, and are intended to be used interchangeably in the present application.

In light of the above, it is now clear that Applicant intends to claim a "tracheotomy endotracheal tube," which is a specific type of endotracheal tube which is inserted into the trachea of a patient via a tracheal stoma. While Applicant does not believe it to be necessary to amend the Specification, a clarifying amendment to the Specification can be made should the Examiner find it necessary to do so. However, in light of the clarification presented above Applicant respectfully requests that the objection to the Specification under 35 USC 112, first paragraph, be withdrawn.

#### **IV. Claim Rejections under 35 USC §112, first paragraph**

Claims 1, 17, 23 and 26 are rejected under 35 USC 112, first paragraph, as based on a disclosure which is not enabling. Specifically, the Examiner asserts that "the applicant has failed to provide dimension and units to the lengths described in claims 1, 17, 23 and 26," and that the "units and dimensions of the distal section, intermediate section and the proximal section of the tubing are critical or essential to the practice of the invention."

For the record, Applicant disagrees with the assertion that units and dimensions are "critical to the practice of the invention." First, the claimed ratios, e.g. the ratio between the length of the distal section to the length of the intermediate section, and the ratio between the length of the proximal section to the length of the distal section, do not require units or dimensions. Indeed, any time a comparison is depicted as a ratio, any units are canceled out. Second, the Specification does not disclose or provide units and dimensions to the lengths described in claims 1, 17, 23 and 26 because units and dimensions are not are critical to the practice of the invention.

Nevertheless, Applicant has amended claims 1, 17, and 23 to exclude the limitation of "the ratio of the length of the distal section to the length of the intermediate section is about 1.0

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to about 2.0, and the ratio between the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0." Claim 26 has been canceled. Because claims 1, 17 and 23 as amended do not require the ratios above, it is now clearer that units and dimensions are not critical to the practice of the invention, and the claims continue to be fully enabled by the Specification as filed. Applicant therefore respectfully requests that the rejection under 35 USC 112, first paragraph be withdrawn.

**V. Claim Rejections under 35 USC §102(b) – rejection of Claims 1 and 3-7**

Claims 1 and 3 through 7 are rejected under 35 USC §102(b) as anticipated by Inglis et al., US Pat. # 5,386,826 ("Inglis"). Regarding independent claim 1 of the present invention, the Examiner asserts that "Inglis discloses an apparatus that comprises a short distal section of the tubing 10, an intermediate section of the tubing, a pre-formed obtuse angle bend in the tube between the distal and intermediate sections, an elongated proximal section of the tubing, a pre-formed abrupt bend in the tube between the intermediate and proximal sections, and an inflatable cuff 11 integrated into the distal section of the tubing, wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0." The current Office Action also includes Inglis' FIG. 1, with additional labeling provided to the drawing by the Examiner.

Applicant respectfully traverses the rejection. To anticipate claim 1, Inglis must disclose each limitation of claim 1. Applicant asserts that (1) Inglis does not disclose a tracheostomy endotracheal tube that is a single tube; and (2) Inglis does not disclose an obtuse-angle bend in its tracheal tube assembly, such that Inglis does not anticipate independent claim 1.

First, Inglis relates to a tracheal tube assembly comprising two separate tubes, an outer tube and an inner cannula that is insertable within and removable from the outer tube. (See column 1, lines 5-7 of Inglis). The object of the Inglis invention is to provide an improved inner cannula to fit within a tracheal tube assembly. (See column 1, lines 35-36 of Inglis). In Inglis, "the tracheostomy tube 1 is of conventional construction having a patient end 10 which, in use, is located in the patient's trachea and has an inflatable cuff 11 that seals the tube with the trachea." (See column 2, lines 7-10 of Inglis). The "inner cannula 2 comprises an inner flexible tube 20..."

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(See column 2, lines 17-18 of Inglis). Thus, the assembly of Inglis requires two tubes, while claim 1 of the present application requires a single tube.

Second, Inglis does not disclose an obtuse-angle bend in the tube. Rather, the Examiner has incorrectly labeled the bend portion 13 in FIG. 1 of Inglis as an obtuse-angle bend. Upon reading Inglis it is clear that, contrary to the labeling by the Examiner of the Inglis tube, the bend portion 13 of Inglis is an abrupt bend portion and not an obtuse-angle bend: "The machine end 12 of the tube 1 extends at approximately right angles to the patient end [10], there being an abrupt bend portion 13 between them." (See column 2, lines 10-13 of Inglis).

Further, it is also apparent that the abrupt bend portion 13 in FIG. 1 is not located between the intermediate and proximal sections of the tube, as is required in claim 1 of the present application. Thus, Inglis does not disclose each element which is required in claim 1. Indeed, Inglis discloses only one bend, the abrupt bend portion 13, in the outer tube. Nowhere does Inglis disclose a pre-formed obtuse-angle bend.

Because Inglis does not disclose a single tracheotomy endotracheal tube comprising a short distal section, an intermediate section, a pre-formed obtuse angle bend between the distal and intermediate sections, an elongated proximal section, and a pre-formed abrupt bend between the intermediate and the proximal sections; and because Inglis does not disclose an obtuse-angle bend at all, Inglis does not disclose each limitation of claim 1. Therefore Applicant respectfully requests that the rejection of claim 1 under 35 USC §102(b) be withdrawn.

Claims 3 through 7 are dependent claims of claim 1. Since, as explained above, Inglis does not disclose each limitation of independent claim 1, then it follows that Inglis also does not disclose each limitation of dependent claims 3 through 7. As such, Applicant respectfully requests that the rejection of claims 3 through 7 under 35 USC §102(b) be withdrawn.

#### **VI. Claim Rejections under 35 USC §103(a) – rejection of Claims 1, 3-11, 15, 17 and 26**

Claims 1, 3-11, 15, 17 and 26 are rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck"). Specifically, the Examiner asserts that "Beck discloses the applicant's invention as claimed with the exception of providing a tubing that comprises a ratio of the length of the distal section of tubing to the length of the intermediate

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section of tubing being about 1 to about 2/1.2 to about 1.8 and the ratio of the length of the proximal section of the tubing to the length of the distal section of the tubing being about 2 to about 4/2.5 to about 3.5. Since Beck discloses accordion pleats 10 between the intermediate section and the distal section it would have been obvious that the length of the distal section and the intermediate section can be adjusted to any desired ratios even to the ones claimed in claims 1, 17, 23 and 26". Applicant notes that claims 1, 3-11, 15, 17 and 26 were rejected; however only claims 1, 17, 23 and 26 are addressed in the above excerpt from the Office Action.

Although the current Office Action cites Beck as the primary prior art reference, it does not cite a secondary prior art reference (i.e. unpatentable over Beck in view of whom?). A *prima facie* 103 rejection typically cites two or more references. Nevertheless, to show a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the reference (or references, when combined). *In Re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant respectfully traverses this rejection, and asserts that the rejection of claims 1, 3-11, 15, 17 and 26 is insufficient to show a *prima facie* case of obviousness, because Beck alone does not teach or suggest all of the claim limitations of the rejected claims. Indeed, the current Office Action states that "Beck discloses the applicant's invention as claimed with the exception of providing a tubing that comprises a ratio of the length of the distal section of tubing to the length of the intermediate section of tubing being about 1 to about 2/1.2 to about 1.8 and the ratio of the length of the proximal section of the tubing to the length of the distal section of the tubing being about 2 to about 4/2.5 to about 3.5," yet attributes to Beck the disclosure of the claimed ratios.

If it were obvious in Beck to include these ratios, then Beck would have disclosed these ratios, or would have taught or suggested that the accordion pleats would allow the sections of the tube to be "adjusted to any desired ratios even the ones claimed in claims 1, 17, 23 and 26." Nowhere does Beck teach or suggest the ability of the accordion pleats to change the length of the tube or to "adjust the tube to any desired ratios." Since no other prior art reference has been cited which teaches or suggests these ratios, the ratios attributed to Beck are unquestionably based upon the Applicant's disclosure, and to attribute Applicant's ratios to Beck is impermissible hindsight. "The teaching or suggestion to make the claimed combination and the

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reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Because the above rejection uses impermissible hindsight to attempt to show a *prima facie* case of obviousness, because Beck alone does not teach or suggest all of the claim limitations of the rejected claims, and because claim 26 has been canceled and claims 1, 3-11, 15, and 17 (and 23) have nonetheless been amended to exclude the limitations of "the ratio of the length of the distal section to the length of the intermediate section is about 1.0 to about 2.0/1.2 to about 1.8 and the ratio of the length of the proximal section of the tubing to the length of the distal section of the tubing being about 2 to about 4/2.5 to about 3.5," Applicant respectfully requests that the rejection of claims 1, 3-11, 15, 17 and 26 under 35 USC 103(a) be withdrawn.

#### **VII. Claim Rejections under 35 USC §103(a) – rejection of Claims 2, 12, 18-20, 23-25**

Claims 2, 12, 18, 19, 20, 23, 24, and 25 are rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Nye, US Patent No. 5,590,647 ("Nye"). The Examiner asserts that "Beck discloses the applicant's invention as claimed with the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape described," and that "it would have been obvious to modify Beck's invention by providing a flexible tube that is made of a thermoplastic material...taught by Nye in order to make it easier for the tube to be placed in a desired position so that it will not be dislodged from the patient and allow OR staff to provide any care needed."

Applicant respectfully traverses this rejection. To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. First, Beck does not disclose the applicant's invention as claimed in claims 2, 12, 18, 19, 20, 23, 24, and 25, even disregarding the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape described. Second, Nye does not cure Beck of its deficiencies in this matter.

Beck teaches a hollow tube made "of semi-rigid material." (See Abstract, and column 3, line11 of Beck). While FIG. 1 of Beck discloses a hollow semi-rigid tube which may be semi-rigid along its entire length, Beck does not teach or suggest a tube with all of the other required

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limitations of claims 2, 12, 18, 19, 20, 23, 24, and 25. A more detailed discussion of why Beck does not anticipate claims 2, 12, 18, 19, 20, 23, 24, and 25 under 35 USC 102 is not applicable here, however, since the present rejection is concerned with the combination of Nye with Beck to make the present invention obvious under 35 USC 103.

Applicant respectfully asserts that Nye teaches away from having the entire tube made of a thermoplastic material preformed to the shape described. The term "flexible," as used by Nye, refers to a portion of the tube "wherein the proximal end of the tracheal tube is capable of being shifted or moved during use." (See Column 3, Lines 23-26 of Nye). More specifically, Nye discloses a "tracheal tube which includes a segment of flexible tubing on the proximal end, the flexible tubing allowing for full 360° rotation of the proximal end relative to the distal end of the tracheal tube." (See column 6, Lines 56-59 of Nye). In contrast, the term "flexible," as used by the Applicant, refers to a tube made of a material that returns to its original shape, no matter how much one tries to shift or move it: "The endotracheal tube herein is typically integrally preformed from a suitable flexible thermoplastic material [...] having sufficient resiliency to return to position following flexure. Thus, although the tube has reasonable flexibility that enables it to conform to the environment rather than compelling the environment to conform to it, bend portions 16 and 20 essentially retain their configuration and are not subject to kinking during the administration of oxygen or an anesthetic." (See paragraph 25 of the specification, as filed.)

Applicant's tube is neither able nor required to be "shifted or moved during use," as Nye's tube is, and Applicant's tube is neither able nor required to "allow for full 360° rotation." Rather, Applicant's tube seeks to fit perfectly with the anatomy of the patient, and is not flexible in the meaning intended by Nye. More importantly, the requirement of the claims for a tube having a pre-formed obtuse-angle bend and a pre-formed abrupt bend, both of which "essentially retain their configuration and are not subject to kinking during the administration of oxygen or an anesthetic," serves to verify that the tube is meant to correspond with the anatomy of the patient and not be rotatable or movable during use.

In light of the above, Applicant respectfully asserts that the rejection of claims 2, 12, 18, 19, 20, 23, 24, and 25 fails to articulate a *prima facie* case of obviousness since not all of the



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limitations of the claims have been met by Beck or Nye, either individually or in combination. Therefore, the Applicant respectfully requests this rejection be withdrawn.

**VIII. Claim Rejections Under 35 USC §103(a) – rejection of Claims 13, 14, 16, 21, and 22**

Claims 13, 14, 16, 21, and 22 are rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 (“Beck”) in view of Joseph, US Patent No. 5,582,167 (“Joseph”). The Examiner asserts that “Beck discloses the applicant’s invention as claimed with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate,” and that “Joseph discloses methods and apparatus for reducing tracheal infection using subglottic irrigation, drainage and servo-regulation of endotracheal cuff pressure that does provide a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate,” such that “it would have been obvious to modify Beck’s invention by providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate as taught by Joseph in order to make it easier to deliver oxygen or any other medication.”

Applicant respectfully traverses this rejection. To articulate a *prima facie* case of obviousness, the art cited against the pending claims must, among other things, teach all the limitations of the rejected claims, and must provide a motivation to combine those references to achieve the claimed invention. See MPEP 2143. Applicant agrees that Beck does not disclose all of the limitations of the claims 13, 14, 16, 21, and 22; however Applicant asserts that Joseph does not provide a motivation to combine its teachings with other prior art to achieve a tracheostomy tube that provides a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. That is, Joseph does not cure Beck of its deficiencies.

While FIG. 1 of Joseph illustrates an endotracheal tube with what appears to be a “Murphy eye” or “port” adjacent to a beveled terminal end, the drawing simply illustrates a small circle at the end of the tube that may or may not be interpreted to be a “port.” Indeed, FIG. 1 of Joseph includes no labeling, description, or explanation of this small circle, either in the

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specification or claims. Thus, since Joseph makes no disclosure of a port other than simply including a small circle as an unlabeled item in FIG. 1, then Joseph can not be construed to adequately provide the required motivation to combine a teaching of a port with another prior art reference.

In light of the above, neither Beck nor Joseph teach all of the limitations of claims 13, 14, 16, 21, and 22. Joseph, illustrating only an unlabeled and un-described small circle at the end of the tube in its FIG. 1, can not be construed to provide a motivation to combine an end port with other references to achieve the claimed invention. Therefore, the proposed combinations described above fail to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection of claims 13, 14, 16, 21, and 22 be withdrawn.

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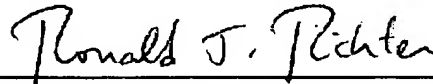
### CONCLUSION

Applicant has addressed each point raised in the non-final Office Action dated 10/04/2005 in the present Response. Therefore, Applicant respectfully requests consideration of this application in view of the foregoing amendments and remarks, and that all the instant claims be duly allowed. The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

Respectfully submitted,

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